REMARKS

The February 7, 2007 Official Action and the references cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the February 7, 2007 Official Action. Therefore, the initial due date for response is May 7, 2007.

As another preliminary matter, the Examiner contends that claim 53 is not fully supported by the parent application (U.S. Patent Application 09/851,327). As such, it is the Examiner's position that the instant application is a continuation-in-part of the '327 application and not a divisional application as recited in the priority claim. Applicants continue to respectfully disagree with the Examiner's position for the reasons of record. However, in the interest of expediting prosecution of the instant application, Applicants have cancelled claim 53. In view of the cancellation of claim 53, the objection to the priority claim of the instant application, the objection to the declaration under 37 CFR §1.67(a), and the objection to the specification under 37 CFR §1.75(d)(1) for allegedly failing to provide antecedent basis for claim 53, have been rendered moot. Withdrawal of these objections is respectfully requested.

The Examiner has also objected to claim 60 under CFR §1.75(c) for allegedly failing to further limit the subject matter of a previous claim. The Examiner has also objected to claim 60 for allegedly encompassing non-elected inventions. Applicants respectfully disagree with the Examiner's position. However, in the sole interest of expediting prosecution of the

instant application, Applicants have cancelled claim 60, thereby overcoming the instant objections.

Claims 68-70 have also been rejected for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

The Examiner has also rejected claims 34, 41-44, 57, 58, and 68 for allegedly failing to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph on two grounds.

Claims 34, 41-45, 52, 53, 55, 59, 60, and 66 have also been rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 5,849,902.

Claims 34, 41, 44, 45, 52-56, 58-60, and 66 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 5,652,225.

Lastly, claims 34, 41, 44, 45, 52-54, 56, 59, 60, and 66 have been rejected under 35 U.S.C. §§102(a) and 102(e) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent 6,025,337.

The foregoing objections and rejections constitute all of the grounds set forth in the February 7, 2007 Official Action for refusing the present application.

In accordance with instant amendment, claims 71-73 have been added. Support for these claims can be found, for example, at page 28, lines 10-11.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the objections to the specification; the objections to claim

60; the 35 U.S.C. §112, first paragraph rejections of claims 34, 41-44, 57, 58, and 68-70; and the 35 U.S.C. §102/103 rejections of claims 34, 41-45, 52-56, 58-60, and 66, as set forth in the February 7, 2007 Official Action, cannot be maintained. These grounds of objection and rejection are, therefore, respectfully traversed.

CLAIMS 68-70 SATISFY THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected claims 68-70 for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph on the following two grounds. First, the Examiner contends that the specification only teaches that the collagen is denatured for 1 hour and not any unspecified period of time. Second, the Examiner contends that the specification does not teach that these denaturation conditions can be employed on types of collagen other than bovine type I collagen.

Applicants respectfully disagree with the Examiner's position. The instant specification teaches that the collagen needs to be denatured (see, e.g., page 14, lines 24-25). It is demonstrated in Example 1 that the collagen can be denatured by boiling the collagen in an acidic environment. While the specific example teaches that the collagen was boiled in acidic conditions for one hour, the length of time can be varied so long as the collagen is denatured, as required by the instant specification. It is a well-established premise that it is improper to limit an application only to the preferred embodiment of the invention.

Additionally, the instant specification clearly teaches at page 14, lines 24-29 that the denatured collagen of the instant invention can be any type of collagen. The teaching at page 28, line 10-11 is a specific example wherein

bovine type I collagen is denatured by boiling in acidic conditions. However, it is clear, based on the teaching at, for example, page 14, that the instant specification encompasses collagen other than bovine type I collagen. Indeed, the specification also states at page 27, lines 13-16 that the Examples "should be construed to encompass any and all variations which become evident as a result of the teaching provided herein."

In view of the foregoing, it is evident that the written description rejections of claims 68-70 are untenable. Applicants respectfully request that these rejections of claims 68-70 be withdrawn.

CLAIMS 34, 41-44, 57, 58, AND 68, AS AMENDED, SATISFY THE ENABLEMENT REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected claims 34, 35, 40-44, 57, 58, and 68 for allegedly failing to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph on the following two grounds.

First, with regard to claims 34, 41-44, and 68 it is the Examiner's position that while the specification is enabling for enhancing transfection of cultured cells in the presence of denatured collagen, the specification allegedly does not provide enablement for any other embodiments embraced by the claims. Applicants continue to disagree with the Examiner's position for the reasons of record. However, in the sole interest of expediting prosecution of the instant application, Applicants have amended claim 34, from which claims 41-44 and 68 depend, to recite that the method is performed *in vitro*. Accordingly, the instant rejection has been overcome.

Second, the Examiner contends that claims 57 and 58 fail to comply with the enablement requirement because the

claimed compositions are "taught in the specification only as being for *in vivo* use." Applicants respectfully disagree with the Examiner's position for the reasons of record. However, in the sole interest of expediting prosecution, Applicants have cancelled claims 57 and 58, thereby rendering the instant rejection moot.

In view of all of the foregoing, Applicants respectfully request that the enablement rejections of claims 34, 41-44, 57, 58, and 68 be withdrawn.

CLAIMS 34, 41-45, 52-56, 58-60, AND 66 ARE NOT ANTICIPATED OR RENDERED OBVIOUS BY THE CITED REFERENCES

The Examiner has maintained the rejections under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) of claims 34, 41-45, 52, 53, 55, 59, 60, and 66; claims 34, 41, 44, 45, 52-56, 58-60, and 66; and claims 34, 41, 44, 45, 52-54, 56, 59, 60, and 66 in view of the '902 patent, the '225 patent, and the '337 patent. Applicants continue to respectfully disagree with the Examiner's position.

At page 11 of the Official Action, the Examiner indicates he was unable to obtain a copy of Tilghman v. Proctor, 102 U.S. 707 (1881). A copy is provided herewith.

The Examiner also contends that the "key limitation" of Rapoport v. Demont "was not only that the compound was used to treat a specific condition but that the compound was administered at a particular time." Applicants respectfully disagree. While the court did consider the timing of the administration of the drug, the court heavily relies on the distinction between treating sleep apnea and treating the symptoms associated with sleep apnea. Indeed, the prior art reference did not even expressly indicate when the drug should be taken, thereby lessening the court's reliance on this point

as a distinction between the patent application and the prior art.

The Examiner also contends that in In re Marshall the "distinguishing feature was the required dosage of the compound." This is incorrect. Indeed, the court's analysis of the rejection under 35 U.S.C. §102 lacks any reference to the concentrations of the composition to be administered. Further, the independent claim of the patent at issue lacks any recitation of the amount of the compound to be administered. Clearly, the court relied on the distinction that the patent claims were to methods of weight control whereas the prior art teaching was directed to inhibition of the release of gastrin. It is this difference that led the court to conclude that an "accidental or unwitting duplication of an invention cannot constitute an anticipation."

The instantly claimed methods, compositions, and kits are directed to enhancing the delivery of a nucleic acid molecule to a cell through the use denatured collagen. As stated in the July 21, 2006 Official Action response, the '902, '225, and '337 patents clearly fail to teach or suggest any enhancement in the efficiency of the delivery of a nucleic acid molecule of the cell in the presence of gelatin.

Notably, amended claim 67, which depends from claim 34, recites the additional step of comparing the expression of the heterologous protein or polypeptide in the presence and absence of denatured collagen to determine the enhancement of the efficiency of delivering the nucleic acid molecule to the cell. Inasmuch as the '902, '225, and '337 patents fail to teach or suggest any enhancement in the efficiency of the delivery of a nucleic acid molecule of the cell in the presence of gelatin, the instantly claimed method can not be considered to be anticipated or rendered obvious by these patents.

Lastly, Applicants note that the Examiner at page 12 of the Official Action states that "there is no indication in the specification that enhancement of transfection requires or depends upon the recited conditions for preparing the gelatin." Applicants respectfully disagree. At page 28, the instant specification clearly teaches that collagen denatured with heat and acidic conditions is superior to native collagen or collagen gelled at pH 7.4 and 37°C with regard to promoting transfection.

In view of all of the foregoing, Applicants submit that the 35 U.S.C. §102/103 rejections of claims 34, 41-45, 52-56, 58-60, and 66 are untenable. Withdrawal of these rejections is respectfully requested.

CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the objections and rejections set forth in the February 7, 2007 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the

Examiner is requested to telephone the undersigned at the phone number given below.

Respectfully submitted,
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